



[BILLING CODE 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed collection; 60-day comment request; Cancer Therapy Evaluation Program (CTEP) Branch and Support Contracts Forms and Surveys (National Cancer Institute)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995 to provide opportunity for public comment on proposed data collection projects, the National Cancer Institute (NCI) will publish periodic summaries of propose projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Michael Montello, Pharm. D., Cancer Therapy Evaluation Program (CTEP), 9609 Medical Center Drive, MSC 9742, Rockville, MD 20850 or call non-toll-free number 240-276-6080 or E-mail your request, including your address to: montellom@mail.nih.gov. Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: Section 3506(c)(2)(A) of the Paperwork

Reduction Act of 1995 requires: written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1)

Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Proposed Collection Title: CTEP Support Contract Forms and Surveys (NCI), 0925-0753

Expiration Date 07/31/2021, REVISION, National Cancer Institute (NCI), National Institutes of Health (NIH).

Need and Use of Information Collection: The National Cancer Institute (NCI) Cancer Therapy Evaluation Program (CTEP) and the Division of Cancer Prevention (DCP) fund an extensive national program of cancer research, sponsoring clinical trials in cancer prevention, symptom management and treatment for qualified clinical investigators. As part of this effort, CTEP implements programs to register clinical site investigators and clinical site staff, and to oversee the conduct of research at the clinical sites. CTEP and DCP also oversee two support programs, the NCI Central Institutional Review Board (CIRB) and the Cancer Trial Support Unit (CTSU). The combined systems and processes for initiating and managing clinical trials is termed the Clinical Oncology Research Enterprise (CORE) and represents an integrated set of information systems and

processes which support investigator registration, trial oversight, patient enrollment, and clinical data collection. The information collected is required to ensure compliance with applicable federal regulations governing the conduct of human subjects research (45 CFR 46 and 21 CFR 50), and when CTEP acts as the Investigational New Drug (IND) holder, FDA regulations pertaining to the sponsor of clinical trials and the selection of qualified investigators under 21 CFR 312.53). Survey collections assess satisfaction and provide feedback to guide improvements with processes and technology.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 151,716.

Estimated Annualized Burden Hours

Form Name	Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Annual Burden Hours
CTSU IRB/Regulatory Approval Transmittal Form (Attach. A01)	Health Care Practitioner	2444	12	2/60	978
CTSU IRB Certification Form (Attach. A02)	Health Care Practitioner	2444	12	10/60	4888
Withdrawal from Protocol Participation Form (Attach. A03)	Health Care Practitioner	279	1	10/60	47
Site Addition Form (Attach. A04)	Health Care Practitioner	80	12	10/60	160
CTSU Request for Clinical Brochure (Attach. A06)	Health Care Practitioner	360	1	10/60	60
CTSU Supply Request Form (Attach. A07)	Health Care Practitioner	90	12	10/60	180
RTOG 0834 CTSU Data Transmittal Form (Attach. A10)	Health Care Practitioner	12	76	10/60	152
CTSU Patient Enrollment Transmittal Form (Attach. A15)	Health Care Practitioner	12	12	10/60	24
CTSU Transfer Form (Attach. A16)	Health Care Practitioner	360	2	10/60	120
CTSU System Access Request Form (Attach. A17)	Health Care Practitioner	180	1	10/60	30
CTSU OPEN Rave Request Form (Attach. A18)	Health Care Practitioner	30	21	10/60	105
CTSU LPO Form Creation (Attach. A19)	Health Care Practitioner	5	2	120/60	20

Form Name	Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Annual Burden Hours
CTSU Site Form Creation and PDF (Attach. A20)	Health Care Practitioner	400	10	30/60	2000
CTSU PDF Signature Form (Attach. A21)	Health Care Practitioner	400	10	10/60	667
NCI CIRB AA & DOR between the NCI CIRB and Signatory Institution (Attach. B01)	Participants	50	1	15/60	13
NCI CIRB Signatory Enrollment Form (Attach. B02)	Participants	50	1	15/60	13
CIRB Board Member Application (Attach. B03)	Board Member	100	1	30/60	50
CIRB Member COI Screening Worksheet (Attach. B08)	Board Members	100	1	15/60	25
CIRB COI Screening for CIRB meetings (Attach. B09)	Board Members	72	1	15/60	18
CIRB IR Application (Attach. B10)	Health Care Practitioner	80	1	1	80
CIRB IR Application for Exempt Studies (Attach. B11)	Health Care Practitioner	4	1	30/60	2
CIRB Amendment Review Application (Attach. B12)	Health Care Practitioner	400	1	15/60	100
CIRB Ancillary Studies Application (Attach. B13)	Health Care Practitioner	1	1	1	1
CIRB Continuing Review Application (Attach. B14)	Health Care Practitioner	400	1	15/60	100

Form Name	Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Annual Burden Hours
Adult IR of Cooperative Group Protocol (Attach. B15)	Board Members	65	1	180/60	195
Pediatric IR of Cooperative Group Protocol (Attach. B16)	Board Members	15	1	180/60	45
NCI Adult/Pediatric Continuing Review of Cooperative Group Protocol (Attach. B17)	Board Members	275	1	1	275
Adult Amendment of Cooperative Group Protocol (Attach. B19)	Board Members	40	1	120/60	80
Pediatric Amendment of Cooperative Group Protocol (Attach. B20)	Board Members	25	1	120/60	50
Pharmacist's Review of a Cooperative Group Study (Attach. B21)	Board Members	50	1	120/60	100
Adult Expedited Amendment Review (Attach. B23)	Board Members	348	1	30/60	174
Pediatric Expedited Amendment Review (Attach. B24)	Board Members	140	1	30/60	70
Adult Expedited Continuing Review (Attach. B25)	Board Members	140	1	30/60	70
Pediatric Expedited Continuing Review (Attach. B26)	Board Members	36	1	30/60	18
Adult Cooperative Group Response to CIRB Review (Attach. B27)	Health Care Practitioner	30	1	1	30

Form Name	Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Annual Burden Hours
Pediatric Cooperative Group Response to CIRB Review (Attach. B28)	Health Care Practitioner	5	1	1	5
Adult Expedited Study Chair Response to Required Modifications (Attach. B29)	Board Members	40	1	30/60	20
Reviewer Worksheet- Determination of UP or SCN (Attach. B31)	Board Members	400	1	10/60	67
Reviewer Worksheet - CIRB Statistical Reviewer Form (Attach. B32)	Board Members	100	1	15/60	25
CIRB Application for Translated Documents (Attach. B33)	Health Care Practitioner	100	1	30/60	50
Reviewer Worksheet of Translated Documents (Attach. B34)	Board Members	100	1	15/60	25
Reviewer Worksheet of Recruitment Material (Attach. B35)	Board Members	20	1	15/60	5
Reviewer Worksheet Expedited Study Closure Review (Attach. B36)	Board Members	20	1	15/60	5
Reviewer Worksheet of Expedited IR (Attach. B38)	Board Members	5	1	30/60	3
Annual Signatory Institution Worksheet About Local Context (Attach. B40)	Health Care Practitioner	400	1	40/60	267
Annual Principal Investigator Worksheet About	Health Care Practitioner	1800	1	20/60	600

Form Name	Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Annual Burden Hours
Local Context (Attach. B41)					
Study-Specific Worksheet About Local Context (Attach. B42)	Health Care Practitioner	4800	1	15/60	1200
Study Closure or Transfer of Study Review Resp. (Attach. B43)	Health Care Practitioner	1680	1	15/60	344
Unanticipated Problem or Serious or Continuing Noncompliance Reporting Form (Attach. (B44)	Health Care Practitioner	360	1	20/60	120
Change of Signatory Institution PI Form (Attach. B45)	Health Care Practitioner	120	1	20/60	40
Request Waiver of Assent Form (Attach. B46)	Health Care Practitioner	35	1	20/60	12
CIRB Waiver of Consent Request Supplemental Form (Attachment B47)	Health Care Practitioner	20	1	15/60	5
Review Worksheet CIRB Review for Inclusion of Incarcerated Participants (Attachment B48)	Board Members	20	1	1	20
Notification of Incarcerated Participant Form (B49)	Health Care Practitioner	20	1	20/60	7
CTSU OPEN Survey (Attach. C03)	Health Care Practitioner	10	1	15/60	3

Form Name	Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Annual Burden Hours
CIRB Customer Satisfaction Survey (Attach. C04)	Participants	600	1	15/60	150
Follow-up Survey (Communication Audit) (Attach. C05)	Participants/ Board Members	300	1	15/60	75
CIRB Board Member Annual Assessment Survey (Attach. C07)	Board Members	60	1	15/60	15
PIO Customer Satisfaction Survey (Attach. C08)	Health Care Practitioner	60	1	5/60	5
Audit Scheduling Form (Attach. D01)	Group/CTMS Users	152	5	21/60	266
Preliminary Audit Findings Form (Attach. D02)	Auditor	152	5	10/60	127
Audit Maintenance Form (Attach. D03)	Group/CTMS Users	152	5	9/60	114
Final Audit Finding Report Form (Attach. D04)	Group/CTMS Users	75	11	1098/60	15098
Follow-up Form (Attach. D05)	Group/CTMS Users	75	7	27/60	236
Roster Maintenance Form (Attach. D06)	CTMS Users	5	1	18/60	2
Final Report and CAPA Request Form (Attach. D07)	CTMS Users	12	9	1800/60	3240
NCI/DCTD/CTEP FDA Form 1572 for Annual Submission (Attach. E01)	Physician	26,500	1	15/60	6625
NCI/DCTD/CTE Biosketch (Attach. E02)	Physician; Health Care Practitioner	48,000	1	120/60	96000

Form Name	Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Annual Burden Hours
NCI/DCTD/CTEP Financial Disclosure Form (Attach. E03)	Physician; Health Care Practitioner	48,000	1	15/60	12000
NCI/DCTD/CTEP Agent Shipment Form (ASF) (Attach. E04)	Physician	24,000	1	10/60	4000
Totals		167,715	276		151,716

Dated: October 1, 2020.

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National Institutes of Health.

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